

Notice of Allowability

Application No.

09/976,437

Applicant(s)

HEROUX ET AL.

Examiner

Art Unit

Suryaprabha Chunduru

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/29/07.
2. ☒ The allowed claim(s) is/are 50-53, 60-65, 69, 85-87 and 95-112.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Suryaprabha Chunduru
SURYAPRABHA CHUNDURU
PRIMARY EXAMINER
1/5/08

DETAILED ACTION

1. Applicants' response and the amendment filed on November 29, 2007 have been considered and entered.

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephanie H. Vavra on January 02, 2008.

Please amend the claims as follows:

Claim 50. A method of assaying a sample for an enzyme activity that joins a first substrate with a second substrate to form a product or for a factor that affects the activity of said enzyme, wherein the presence, concentration, or activity of said enzyme or said factor is not known, comprising:

(a) forming a composition comprising said sample, said first substrate and said second substrate, said first substrate being linked to a luminescent label and said second substrate being linked to a capture moiety;

(b) incubating said composition under conditions wherein said enzyme can form said product at a differing rate in the presence or absence of said enzyme or factor, wherein said product is linked to said luminescent label and said capture moiety and wherein said enzyme or factor is not a part of the product;

- (c) capturing said capture moiety on an electrode;
- (d) applying voltage at said electrode so as to induce said luminescent label in said product to emit luminescence; and
- (e) measuring emitted luminescence so as to measure the presence of said enzyme or factor in said sample,

wherein said enzyme is selected from the group consisting of nucleic acid polymerases, nucleic acid ligases, integrases, ribosomes, and trans-glutaminases.

Claim 64. The method of claim 60, wherein said enzyme is selected from the group consisting of nucleases, proteases and glycosidases.

Claim 87. The method of claim 50, wherein said factor is selected from the group consisting of an enzyme, an enzyme inhibitor, a denaturing compound, an enzyme activator, an enzyme deactivator, and a co-enzyme.

Claim 98. The method of claim 60, wherein said factor is selected from the group consisting of an enzyme, an enzyme inhibitor, a denaturing compound, an enzyme activator, an enzyme deactivator, and a co-enzyme.

Claim 111. The method of claim 50, wherein said enzyme is selected from the group consisting of nucleic acid polymerases, nucleic acid ligases, integrases and ribosomes.

Claim 112. The method of claim 50, wherein said enzyme is a trans-glutaminase.

4. The following is an examiner's statement of reasons for allowance:

Claims 50-53, 60-65, 69, 85-87, 95-112 are allowed.

The present invention is drawn to a method of assaying a sample for enzyme activity that joins a first substrate with a second substrate to form a product or for a factor that affects the

activity of said enzyme and a method of assaying a sample for an enzyme activity that cleaves a substrate or for a factor that affects the activity of said enzyme comprising forming a composition comprising said sample and said substrate(s) wherein substrate(s) linked to a luminescent label and as solid phase or a capture moiety, incubating said composition under condition wherein said enzyme joins said substrates to form a product / or cleave a substrate, immobilizing said product linked to the label on to an electrode, applying a voltage at said electrode and measuring the emitted luminescence to measure the presence of said enzyme or factor in the sample. The closest prior art Wohlstadter et al. teach a method for assaying an enzyme activity, however, the prior art does not teach the enzyme activity of said enzymes that joins a first substrate with a second substrate as reflected by the instant amended claim 50 and does not teach a method of assaying an enzyme activity that cleaves a substrate using non graphitic nanotube as reflected in claim 60. Thus the instant invention was not taught or obvious over the closest prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637


SURYAPRABHA CHUNDURU 1/5/08
PRIMARY EXAMINER